

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19777/S24

CHEMISTRY REVIEW(S)

MAY 15 1995

CHEMIST'S REVIEW		1. ORGANIZATION HFD-110	2. NDA Number 19-777
3. Name and Address of Applicant (City & State) Zeneca Pharmaceuticals Group Wilmington, DE 19897		4. Supplement(s) Number(s) Date(s) S-024 18 Nov 94	
5. Drug Name Zestril	6. Nonproprietary Name Lisinopril	7. Amendments & Other (reports, etc) - Dates	
8. Supplement Provides For: Transfer of testing of the drug substance and drug product from the existing laboratories in Guayama and Carolina, PR to a new laboratory facility at the Guayama location.			
9. Pharmacological Category Antihypertensive	10. How Dispensed <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC	11. Related IND(s)/ NDA(s)/DMF(s) NDA 19-558 Prinivil, Merck	
12. Dosage Form(s) TCM	13. Potency(ies) 2.5, 5, 10, 20, 40 mg		
14. Chemical Name and Structure		15. Records/Reports Current <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Reviewed <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
16. Comments: An EER requesting inspection of the new testing facility at the Guayama location was sent to HFD-324 on 22 Nov 95. I was informed by E Mail on 12 May 95 by Mimi Egas, HFD-324, that SJN-DO had found that the facility was not acceptable because all the equipment was not yet in place.			
17. Conclusions and Recommendations: NOT APPROVABLE is recommended.			
18.			
Name James H. Short		Date Completed 12 May 95	
Distribution: <input type="checkbox"/> Original Jacket <input type="checkbox"/> Reviewer <input type="checkbox"/> Division File <input type="checkbox"/> CSO <input type="checkbox"/> District			

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R/D Init: RWolters/5/12/95